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MAY - 6 2004

510(k) SUMMARY

NAME OF FIRM:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46580

510(K) CONTACT:

Natalie S. Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME:

DePuy Pinnacle® Acetabular Cup System
ESL Marathon™ Polyethylene Liners
DePuy Ultima™ Unipolar Femoral Heads
DePuy Self-Centering™ Hip Prosthesis

COMMON NAME:

Acetabular Cup Liner
Femoral Head

CLASSIFICATION:

Class II, per 21 CFR, 888.3358
Hip joint metal/polymer/ metal, semi-constrained, porous-coated, uncemented prosthesis

DEVICE PRODUCT CODE:

87 LPH

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Pinnacle® Acetabular Cup System
Marathon™ Cross-Linked Polyethylene Liners
Biomet Tri-polar System
DePuy Ultima™ Unipolar Femoral Heads
Depuy Self-Centering™ Hip Prosthesis

DEVICE DESCRIPTION:

The Pinnacle® Acetabular System is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from cross-linked ultra high molecular weight polyethylene (UHMWPE), which locks into the outer shell. The liner component articulates with a femoral head of an appropriate diameter.

The subject Pinnacle® Enhanced Stability (ESL) Marathon™ liners are cross-linked UHMWPE acetabular cup liners that are available in a lateralized neutral, or lateralized face-changing orientation. The liners have inner diameters (ID) intended for use with modular, unipolar, or self-centering (bipolar) femoral heads within the 28mm-48mm size range. The outer diameters

geometrically the same as other Pinnacle Acetabular Cup Liners, in a 44mm-76mm size range offering. There is an addition of a Charnley-style bore on sizes 36mm-48mm ID to increase stability.

The Ultima™ Unipolar femoral head is provided in a size range of 38mm to 63mm OD, in 1mm increments. The subject heads have a tapered bore which can receive a variety of adapter sleeves, originally cleared in K965156 (01-24-07) which are machined from CoCrMo alloy in wrought bar. The femoral head is also used in total hip arthroplasty when used in conjunction with a UHMWPE bearing surface having an inside diameter corresponding to the outside diameter of the modular femoral head that is utilized.

The Self-Centering™ Hip Prosthesis is a component consisting of a metallic cup and an UHMWPE insert and plastic retaining ring. It is used with a DePuy femoral hip stem and modular metal ball with a head diameter corresponding to the inside diameter of the Self-Centering™ Hip polyethylene insert (22mm - 28mm), to replace the femoral head and neck. The Self-Centering Hips are provided in a size range of 39mm through 57mm OD, in 2 mm increments. The bearing inserts are offered in two inner diameters, to accept 22mm and 28mm femoral components. The Self-Centering Hip is being submitted as part of a Total Hip Prosthesis when used in conjunction with a UHMWPE bearing surface having an inside diameter corresponding to the outside diameter of the metallic cup that is utilized.

INDICATIONS AND INTENDED USE:

Intended Use:

The subject ESL Marathon™ Polyethylene Liners are intended to be used with the DePuy Pinnacle® metal acetabular shells, modular femoral heads, unipolar femoral heads, and self-centering heads to resurface the acetabular socket in cementless total hip arthroplasty.

The subject Ultima™ Unipolar and the Self-Centering™ Hip Prosthesis, originally cleared for hemi-arthroplasty procedures, are also intended for use in total hip replacement when used in conjunction with a metal backed UHMWPE bearing surface having an inside diameter corresponding to the outside diameter of the metallic head/cup that is utilized.

Indications:

The Pinnacle® Enhanced Stability Liner is indicated for use in total hip replacement procedures. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Pinnacle® ESL is indicated for use with the Pinnacle® Acetabular Cup in cementless application.

Indications for the Ultima™ Unipolar heads and the Self-Centering™ Hip Prostheses previously cleared for Hemi-Hip Arthroplasty remain unchanged. Additions to the indications for use include:

Self-Centering™ Hip Prostheses and unipolar femoral heads are also intended to be used for total hip arthroplasty to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components, when used in conjunction with a UHMWPE bearing surface having an inside diameter corresponding to outside diameter of the metallic cup that is utilized. Use in total hip replacement is indicated in the following additional conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia

2. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty ,or total hip replacement.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Pinnacle® ESL Marathon Polyethylene Liners (lateralized neutral and lateralized face-changing), Ultima™ Unipolar and Self-Centering devices described in this submission are substantially equivalent to the predicate devices based on similarities in design, intended use, material and manufacturing methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2004

Ms. Natalie Heck
Manager, Regulatory Affairs
Depuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K033273
Trade/Device Name: Pinnacle® Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: February 10, 2004
Received: February 11, 2004

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS

510(k) Premarket Notification

510(k) Number (if known) K033273

Device Name: Pinnacle® Acetabular System

Indications for Use:

The Pinnacle® Enhanced Stability Liner (ESL) is indicated for use in total hip replacement procedures. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The Pinnacle® ESL is indicated for use with the Pinnacle® Acetabular Cup in cementless application.

(cont.)

Concurrence of CDRH, Office of Device Evaluation:

for Mark A Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033273

Prescription Use ✓ or Over-The-Counter Use ✗ (Per 21 CFR 801.109)